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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,446	01/28/2004	Douglas G. Vanderlaan	VTN5537DIV	3191
27777	7590	03/24/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			PENG, KUO LIANG	
			ART UNIT	PAPER NUMBER
			1712	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

an

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/766,446	VANDERLAAN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kuo-Liang Peng	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12/29/05 Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21, 23 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23 and 75-80 is/are rejected.
- 7) ☒ Claim(s) 2 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/1/05, 11/16/05</u>  | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The Applicants' amendment filed on December 29, 2005 was received. Claims 22 and 24-74 are deleted. Claim 76 is amended. Now, Claims 1-21, 23 and 75-80 are pending.
2. Claim objection(s) in the previous Office Action (Paper No. 080605) is/are removed.
3. Claim rejection(s) under double patenting rejection in the previous Office Action (Paper No. 080605) is/are removed.
4. The indicated allowability of Claims 1-21, 23 and 76-80 is withdrawn in view of the new ground of rejection based on Spinelli (US 5 314 960). Rejections based on the new ground follow. Examiner apologies for causing any inconvenience.
5. The text of those sections of Title 35, U.S. code not included in this action can be found in prior Office Actions.

***Claim Objections***

6. Claims 2 and 17 are objected to because of the following informalities:

In Claim 2 (line 1), should “b is about” be -- be is from about --?

In Claim 17 (line 1), “comprising” appears to be improper because O2 DK is a property of the material, not a component.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. Rejection of Claims 1-11, 13-21, 23 and 75-78 under 35 USC 112 is maintained because the rejection is adequately set forth in paragraph 8 of Paper No. 080605. Applicant's arguments have been fully considered but they are not persuasive. The focus argument related to the core patentability is discussed below.

In view of Applicants' argument (Remarks, page 8), it is still not clear as to what “less than about 0.1 to no more than about 0.3” refers to.

***Claim Rejections - 35 USC § 102***

8. Claims 1-21, 23 and 75-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Spinelli (US 5 314 960).

Spinelli discloses a method for preparing silicone hydrogel derived from monomers including the (meth)acryl-containing silicone monomer described in Figures 1A-1C, col. 7, lines 18-37. (col. 6, line 3 to col. 9, line 68 and Examples) Note that lowering the Young's modulus and/or  $\tan \delta$  **to the specific ranges set forth in the present invention** is an inherent outcome due to the incorporation of the instant (meth)acryl-containing silicone monomer because **Applicants' specification admits** that when mPDMS is present in an amount between about 2 and 70wt% based on total weight of reactive monomer, depending on the other monomers present, this will generally reduce the modulus and  $\tan \delta$  to the specific claimed ranges. (page 7, last paragraph to page 8, 1<sup>st</sup> paragraph). Furthermore, note that Spinelli's monomer described in col. 7, lines 13-38 is present in an amount falling within the aforementioned amount range of Applicants' mPDMS because Spinelli's macromonomer can be derived from a monomer mixture comprising the aforementioned Spinelli's monomer in an amount described in col. 7, lines 13-38 and the macromonomer can be in an amount as described in col. 9, lines 45-59. For Claims 9-11 and 76-78, Spinelli further teaches the use of a mixture of TRIS and other (meth)acryl-containing silicone monomers such as n-pentylhexamethyltrisiloxanylmethylmethacrylate, etc. (col. 17, lines 4-41)

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9. Claims 1, 6-18, 21, 23 and 75-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Lai (WO 93/09154).

The following column and line numbers are based on Lai's US equivalent, US 5 486 579.

Lai a method for preparing silicone hydrogel derived from monomers including the (meth)acryl-containing bulky silicone monomer such as TRIS, pentamethyldisiloxanylmethyl methacrylate, phenyltetramethyldisiloxanylethyl acrylate, di(trimethylsiloxy)methacryloxymethyl silane, etc. (col. 2, lines 3-26, col. 4, lines 60-64 and Examples) Note that the bulky silicone monomer can be used in an amount of 30 parts. (Examples 1-6) Note that lowering the Young's modulus and/or  $\tan \delta$  to the specific ranges set forth in the present invention is an inherent outcome due to the incorporation of the instant (meth)acryl-containing bulky silicone monomer because **Applicants' specification admits** that when mPDMS is present in an amount between about 2 and 70wt% based on total weight of reactive monomer, depending on the other monomers present, this will generally reduce the modulus and  $\tan \delta$  to the specific claimed ranges. (page 7, last paragraph to page 8, 1<sup>st</sup> paragraph).

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10. Claims 1, 6-18, 21, 23 and 75-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama (EP 461 270).

Yokoyama discloses a method for preparing silicone hydrogel derived from monomers including the (meth)acryl-containing silicone monomer such as TRIS, pentamethyldisiloxanylmethyl methacrylate, bis(trimethylsiloxy)methylsilylpropyl methacrylate, etc. (Table 1 and Examples) Note that the aforementioned silicone monomer can be used in an amount falling within the claimed amount range of Applicant's mPDMS. Note that lowering the Young's modulus and/or  $\tan \delta$  to the **specific ranges set forth in the present invention** is an inherent outcome due to the incorporation of the instant (meth)acryl-containing bulky silicone monomer because **Applicants' specification admits** that when mPDMS is present in an amount between about 2 and 70wt% based on total weight of reactive monomer, depending on the other monomers present, this will generally reduce the modulus and  $\tan \delta$  to the specific claimed ranges. (page 7, last paragraph to page 8, 1<sup>st</sup> paragraph).

11. Claims 1-21, 23 and 75-78 are rejected under 35 U.S.C. 102(b) as being anticipated by Vanderlaan (EP 940 693).

Vanderlaan discloses a method for preparing silicone hydrogel derived from monomers including the (meth)acryl-containing silicone monomer of structures I , II and/or III ([0011], [0016]-[0017] and Examples) Note that lowering the Young's modulus and/or  $\tan \delta$  **to the specific ranges set forth in the present invention** is an inherent outcome due to the incorporation of the instant (meth)acryl-containing silicone monomer because **Applicants' specification admits** that when mPDMS is present in an amount between about 2 and 70wt% based on total weight of reactive monomer, depending on the other monomers present, this will generally reduce the modulus and  $\tan \delta$  to the specific claimed ranges. (page 7, last paragraph to page 8, 1<sup>st</sup> paragraph). Furthermore, note that the aforementioned Vanderlaan's silicone monomer is present in an amount falling within the aforementioned amount range of Applicants' mPDMS ([0029]-[0030] and Examples) For example, monomer T1 can be used in an amount of 35% as described in Table 3.

12. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on November 16, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS**



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**ACTION IS MADE FINAL.** See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (571) 272-1091. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski, can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an

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application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

klp

March 17, 2006



Kuo-Liang Peng  
Primary Examiner  
Art Unit 1712